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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,444	02/17/2004	Peter M. Bonutti	782-A03-023	2789

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EXAMINER

SZPIRA, JULIE ANN

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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08/09/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/780,444	Applicant(s) BONUTTI ET AL.	
	Examiner JULIE A. SZPIRA	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-11,13-24,49-72 and 74-77 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,18-24,49-72 and 74-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/2010 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

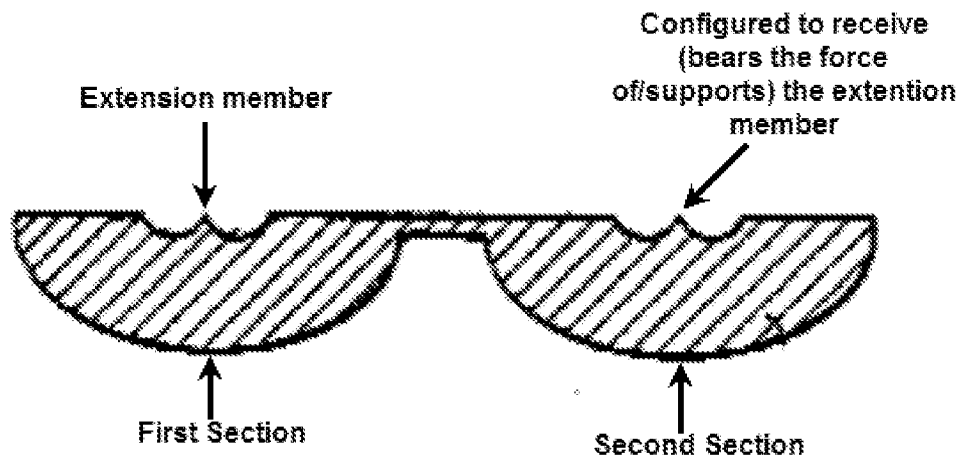
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 18, 19, 24, 49, 53, 54, 58-60, 62-72 and 75-77 are rejected under 35 U.S.C. 102(b) as being anticipated by **Egan et al. (US 6,174,324)**.

Regarding claims 1, 4, 5, 24, 70, 71 and 77, Egan et al. discloses a device that is capable being implanted and securing an object relative to a body tissue within the body comprising a first section including a first surface and an extension member extending from that surface, and a second section including a second surface opposing the first surface and being configured for receiving the extension member (See Figure Below) the first and second section being bondable together with the application of an

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energy source (ultrasonic energy; column 2, lines 27-32 and column 5, lines 23-37), the first surface being configured to abut the object and said second surface being configured to abut the object, said first and second surfaces move closer to each other with the application of the energy source because the extension member shortens (the sections melt, and therefore would mold together, becoming closer) operative to press the object as said first and second sections are bonded together, thereby securing the object within the retainer, whereby the object extends through the fastener in a substantially unobstructed linear fashion (Figures 8 and 12), wherein the first second includes a pair of parallel channels for carrying a first portion of the object in a first of the pair of the parallel channels and for carrying a second portion of the object in a second of the pair of parallel channels (Figure 8; element 112) wherein the extension member is interposed between the pair of parallel channels (see Below).



Regarding claim 18, Egan discloses the first and second sections being textured to enhance the retention and tension of the suture strands within the device (column 4, lines 47-51).

Regarding claim 49, Egan et al. discloses the first and second surfaces configured to sandwich the suture (Figure 12).

Regarding claims 53 and 54, Egan et al. discloses an elongated suture (104).

Regarding claims 58-60, 64, 72, Egan et al. discloses said extension member is compressible (melts to a shorter height) to a height about equal to a thickness of the object to be secured (sandwiches the object between the first and second sections; column 6, lines 10-17) during the application of the energy source to move said first surface and said second surface closer to each other (column 2, lines 27-32), and the extension member is bonded to said second surface (column 5, lines 14-17).

Regarding claims 62 and 63, Egan et al. discloses the fastener is rigid when the energy source is not being applied (column 6, lines 19-25; the fastener becomes part of the bonded loop to provide compressive force), and the object secured relative to the body is a rigid object (the melting of the suture strands and the first and second sections together will immobilize the portion of the object being secured, thus causing the object to be rigid).

Regarding claims 65-67, Egan et al. discloses the first section has a top surface opposing said first surface, said top surface being configured to contact the energy source (Figure 8), and said second section has a bottom surface opposing said second surface, said bottom surface being configured to contact an anvil when said top surface is contacting the energy source (the surface is flat, and therefore could contact an anvil during application of ultrasonic energy), wherein the energy source is an ultrasonic end effector (110).

Regarding claim 69, claim 69 is dependent upon a cancelled claim (claim 3) and thus is considered incomplete. As such, this claims has not been further treated on the merits thereof. See MPEP 608.01(n)

Regarding claim 70, Egan et al. discloses the object extends through the fastener in a substantially linear fashion (Figure 8).

Regarding claim 76, Egan et al. discloses the second surface changes shape (the surface melts) as energy is applied to the fastener (column 2, lines 27-32).

Regarding claim 68, Egan et al. discloses the extension member is fin shaped (Figure 11; the extension member is raised relative to the first surface and comes to a "tip", like a fin).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

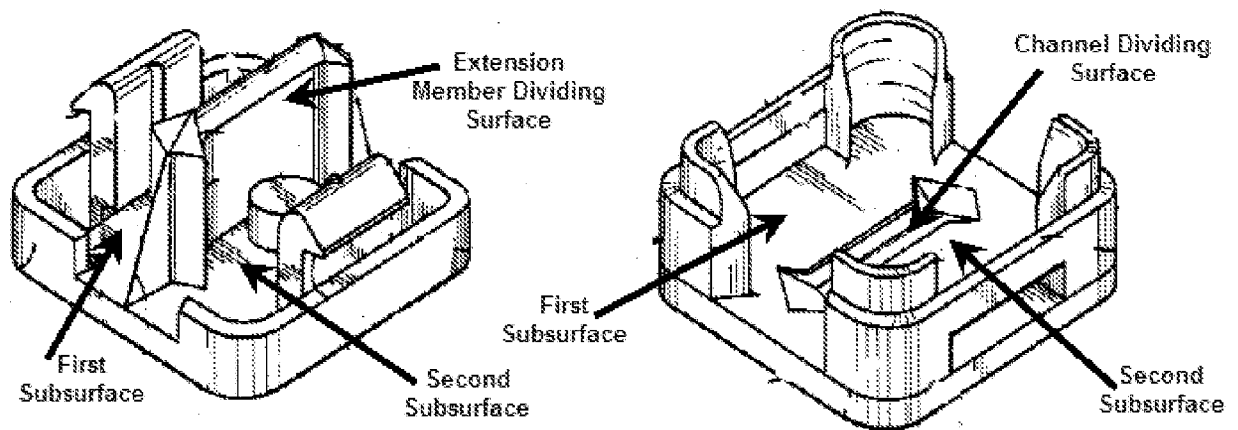
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 8, 50, 51, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan et al. (US 6,174,324)** in view of **Merritt (US 5,208,950)**.

Regarding claims 6, 8, 50, 51, 52, Egan et al. discloses the invention substantially as claimed above, but fails to disclose the second section comprising a channel for receiving the extension member.

However, Merritt discloses the second section including a channel (recess, 35) configured for receiving the extension member (column 3, lines 56-59), the object interposed between the first and second sections when the extension member is positioned within the channel (column 4, lines 16-20), the first section has two channels (76) formed therein, said channels being disposed opposingly about and immediately adjacent to said extension member and the second section is configured to seat within the channels of the first section (Figure 3) and said extension member divides said first surface into a first first-surface subsurface and a second first-surface subsurface, a channel divides said second surface into a first second-surface subsurface and a second - surface subsurface (See Figure Below), said first first-surface subsurface is configured to align with said first second-surface subsurface when said first section is bonded to said second section; and said second first-surface subsurface is configured to align with said second second-surface subsurface when said first section is bonded to said second section (Figure 3), wherein an object is disposed between at least one of said first subsurfaces and at least one of said second subsurfaces (Figure 1)



It would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the second section of Egan et al., the extension member receiving channel of Merritt, to provide a more secure location for which the extension member can bond, thus creating a more secure fastener for the object interposed between the first and second sections.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan et al. (US 6,174,324)** in view of **Hart (US 5,630,824)**.

Regarding claim 20, Egan et al. discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of a biodegradable material.

However, Hart teaches a suture retainer (attachment device) made of a biodegradable polymer (column 4, lines 50-52).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a biodegradable material so the

device can dissolve after the wound which the suture is attached to heals (column 4, lines 52-65).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan et al. (US 6,174,324)** in view of **Tokushige et al. (US 5,866,634)**

Regarding claim 21, Egan et al. discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of heat shrink material.

However, Tokushige et al. teaches a biodegradable shrink material that has superior strength, flexibility, and the ability to shrink at lower temperatures (column 1, lines 39-42; column 4, lines 19-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder of Egan et al. out of a heat shrink material because it would allow the suture retainer to shrink around the suture (container) with minimal warping (column 3, lines 24-26).

The “lower temperature” that affects the shrink material that is disclosed by Tokushige is advantageous for a device intended to be used within or near a human body as the device will have the physical prosperities that are desirable with heating, but not need a tremendous temperature change for the change to occur. This is prevent accidental singeing or burning of a patient during the application of heat, as the heat will not be required to be tremendously high.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan et al. (US 6,174,324)** in view of **Bartlett (US 5,879,372)**.

Regarding claim 22, Egan et al. discloses the invention substantially as claimed above, but fails to disclose the suture retainer including viable cells.

However, Bartlett teaches the suture retainer (anchor) including viable cells (bone tissue) (column 4, lines 34-36 and 46-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include viable cells to strengthen the area in which the device is placed (column 4, lines 24-26).

Claim 23 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan et al. (US 6,174,324)** further in view of **Rhee et al. (US 5,752,974)**.

Regarding claims 23 and 74, Egan et al. discloses the invention substantially as claimed above, but fails to disclose the suture retainer including a pharmaceutical agent, wherein that agent is osteoinductive

However, Rhee et al. teaches the closure material containing a pharmaceutical agent that is osteoinductive (causes cell growth) such as a growth factor (column 6, line 58-column 7, line 23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a pharmaceutical agent to exert biological effects in vivo, such as the promotion of cell growth (column 6, lines 58-62).

Claims 55-57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Egan et al. (US 6,174,324)**.

Regarding claims 55-57, Egan et al. discloses the invention substantially as claimed above, including securing an object relative to body tissue but fails to disclose the object being body tissue or metallic.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the object body tissue or metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Furthermore, the device as claimed is capable of securing a variety of material and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Parte Masham, 2 USPQ F.2d 1647 (1987).

Regarding claims 61, Egan et al. discloses the invention substantially as claimed above, but fails to specifically disclose the fastener material being biocompatible.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the fastener biocompatible, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Furthermore, the fastener disclosed by Egan et al. is used in close proximity to a suture wound closure, and in order to aid in healing, and to not irritate the wound, the use of a biocompatible material would be obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed 12/04/2009 and 7/30/2010 have been fully considered but they are not persuasive.

Regarding Egan et al, the citation by the applicant regarding the ultrasonic welding causing melting of the suture strands is correct, however, the specification of Egan et al. points out more than one way that the fastener functions. In column 2, lines 27-32, Egan et al. discloses that the fastener is made from a material that is melted upon application of ultrasonic energy, thus effecting a bond between the melted portions of the fastener as well as a bond to the suture strand material. Egan et al. discloses various embodiments of how the fastener can be joined to the suture strands, and while the applicant has pointed out the shortcomings of one embodiment, there is another embodiment that meets the claim limitations as currently written.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Szpira whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Friday, 10AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to:

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./
Examiner, Art Unit 3731
July 31, 2011

/S. Thomas Hughes/
Supervisory Patent Examiner, Art Unit 3731